

Board of Pharmacy

Final Statement of Reasons

Subject Matter of Proposed Regulation: Pharmacists: Requirements for Examination;
and Pharmacist Interns: Application Requirement

Title 16 Sections Affected: Add Section 1727.2 to Article 3 of Division 17 of Title 16 of
the California Code of Regulations
Amend Section 1728 in Article 3 of Division 17 of Title 16
of the California Code of Regulations

Updated Information

The Initial Statement of Reasons is included in this rulemaking file. The information contained therein accurately reflects the board's position regarding the adoption of the above sections, but is updated to include the following information.

The board's notice indicated that the board did not intend to hold a hearing on the matter, unless requested. No request for hearing was received by the board.

No objections or recommendations directed at the proposed action were received during the 45-day public comment period from May 6, 2011 to June 20, 2011. The board did receive, however, one comment during the 45-day comment period, requesting clarification of a term used in existing regulation. This comment is addressed further, below.

Self-Query from the National Practitioners Data Bank-Healthcare Integrity and Protection Data Bank

The Initial Statement of Reasons stated that the proposed regulation would require an applicant to submit to the board with his or her application a sealed Self Query Report from the National Practitioner Data Bank-Healthcare Integrity and Protection Data Bank (NPDB-HIPDB). As part of the underlying data, the board – in part – relied on the NPDB-HIPDB "Fact Sheet on Self-Querying" (Fact Sheet dated March 2010, NPDB-00937.10.02) for information related to the procedure, cost, and process by which a practitioner could request and receive a self-query to satisfy the requirement. In December 2010, the NPDB-HIPDB redesigned its Web site. The board learned during the 45-day public comment period that the NPDB-HIPDB removed from its Web site the Fact Sheet referenced by the board in its rulemaking.

The NPDB-HIPDB Web site is comprised of information related to both the National Practitioner Data Bank (NPDB) and the Healthcare Integrity and Protection Data Bank (HIPDB); together, the organizations refer to itself as the "Data Banks."

Through its Web site, the NPDB-HIPDB provides information so that practitioners understand the information available from the NPDB-HIPDB. The site provides answers

to frequently asked questions, instructs practitioners on the process to submit a request for a self-query report, and other information.

The National Practitioner Data Bank (NPDB) is one of a number of efforts to inform the health care community about what is required to comply with the requirements established by the *Health Care Quality Improvement Act of 1995, Public Law 99-660*. Authorized users of information reported to NPDB include state licensing authorities, medical malpractice payers; hospitals and other health care entities; and physicians, dentists, and other licensed healthcare practitioners.

The Healthcare Integrity and Protection Data Bank (HIPDB) was established through the *Health Insurance Portability and Accountability Act of 1996 (HIPPA), Public Law 104-191*. The HIPDB is a national data collection program for reporting and disclosing certain final adverse actions taken against health care practitioners, providers, and suppliers.

To alleviate the burden on entities that must report to both the NPDB and the HIPDB, a system was created to allow an entity that must report the same adverse action to both Data Banks to submit the report only once.

Sections 1921 and 1128E of the Social Security Act require the Board of Pharmacy, as a state licensing authority, to submit adverse licensing and certification actions, as well as negative actions and findings taken against health care practitioners. The Board of Pharmacy reports this information electronically through the NPDB-HIPDB Web site. The Data Banks determine in which system (HIPDB or NPDB) the information resides.

The NPDB-HIPDB Web site guides a practitioner on how to request a Self-Query. From the NPDB-HIPDB main Web page, a person would select services for a "Practitioner" or for an "Organization." The person seeking a self-query report of information on his- or herself would begin by selecting services from the "Practitioner" section of the Web site. As indicated on the former Fact Sheet, the practitioner initiates a self-query request through the NPDB-HIPDB Web site. The practitioner must indicate as part of the self-query request that he/she elects to receive a paper copy (in addition to an electronic response). The practitioner must print the self-query request, sign and date it in the presence of a notary public, and mail the notarized self-query to the address specified by the NPDB-HIPDB. Upon receipt of the notarized self-query request, the NPDB-HIPDB would then process the self-query and electronically alert the practitioner via e-mail that the self-query is available for on-line viewing. Also, if so elected, the NPDB-HIPDB would issue a paper copy of the self-query to the practitioner. As specified in the regulation adopted by the board, the applicant must include with his or her application a sealed, original Self-Query from the NPDB-HIPDB dated no earlier than 60 days of the date an application is submitted to the board.

Local Mandate:

None.

Business Impact:

This regulation will not have a significant adverse economic impact on businesses. This determination was based on the absence of comments or testimony indicating adverse economic impact regarding this rulemaking proposal.

Specific Technologies or Equipment:

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives:

No reasonable alternative to the regulation would be either more effective in carrying out the purpose for which the action is proposed or would be as effective as and less burdensome to the affected persons than the proposed regulation.

Summary of Comments Received During the 45-Day Comment Period (Objections or Recommendations/Responses):Comment by Richard I. Sakai, Pharm.D., Director of Pharmacy Services

Dr. Sakai asks for clarification of the term “recognized school of pharmacy” as is used in existing regulation at 16 CCR § 1728(a). The board did not propose any modifications to subdivision (a) of Section 1728 as part of the rulemaking.

Board Response

The board defines the term “Recognized Schools of Pharmacy” at Title 16 CCR Section 1719. The board did not propose any modifications to 16 CCR 1719 as part of the rulemaking.

Title 16 California Code of Regulations Section 1719:

As used in this division, “recognized school of pharmacy” means a school of pharmacy accredited, or granted candidate status, by the Accreditation Council for Pharmacy Education or otherwise recognized by the board.”